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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,651	11/29/2006	Heno Perillo	4705-0120PUS1	5789
2292 7590 12/11/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
FINN, MEGHAN R				
ART UNIT		PAPER NUMBER		
1614				
NOTIFICATION DATE		DELIVERY MODE		
12/11/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/580,651

Applicant(s)

PERILLO ET AL.

Examiner

MEGHAN FINN

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-53 is/are pending in the application.
- 4a) Of the above claim(s) 47-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/22)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

Applicant's Amendment filed July 23, 2009 has been received and entered into present application. Claims 40-43 were canceled and claims 48-50 were added by applicant. Applicant's Supplemental Amendment filed September 02, 2009 has been received and entered into the present application. Claims 51-53 have been added. Claims 47-53 are withdrawn for pertaining to the non-elected invention and thus claims 44-46 are pending.

Applicants' arguments, filed July 23, 2009 and September 02, 2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to applicant's argument about restriction requirement

In the last office action dated January 23, 2009 it was indicated that the restriction requirement was made final. Applicant has amended the claims and added new ones and argued that since they have established a better link between the product and the process claims that the restriction should be withdrawn. This argument is not found persuasive, because the restriction requirement was made final and is therefore not open to amendments and further arguments and also because even though

applicant feels they have established a better link between the two the basis of the restriction still applies. A product and a process of making have different special technical features and applicant has not demonstrated otherwise. Thus the newly added claims 48-53, as well as the previously submitted claim 47, which are drawn to the process of making are withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US 5,378,475, already of record on pages 4-6 of the previous office action

mailed January 23, 2009 the reasons of which are herein incorporated by reference) in view of Harris et al. (US 4,670,258) in further view of Muller et al. (US 6,027,776).

Applicant's translation of their priority document renders the previous rejection of claims 44-46 moot because Perillo et al. is after the current effective filing date of November 28, 2003 established by that translation.

Applicant is claiming a pharmaceutical formulation comprising an injectable aqueous solution of gancyclovir produced by the process of claims 48-53, diluted in either 5% glucose or 0.9% sodium chloride with a pH ranging from 3.0 to 6.9 and packed in a flexible bag that is composed by three layers the external layer of polyester, intermediate layer of polyethylene, and an inner layer of propylene copolymer. As discussed previously, the claims are drawn to a product, even a product by process claim is a product and if the same product can be made by a different process it will read upon that product by process claim. Smith et al. teaches gancyclovir (also referred to as ganciclovir) as a free acid form (column 12, lines 55-60) and teaches it in a buffer solution of 0.65% sodium chloride (column 12, lines 61-63). Applicant has not argued that the gancyclovir of Smith et al. does not render the gancyclovir of the instant claims 44-46 obvious. The solution of Smith et al. is an injectable solution and gancyclovir is well known in the art as a drug that is administered intravenously. It is also well known in the art that drug administered intravenously are diluted in either 5% glucose or a saline (0.9% sodium chloride) solution as evidenced by Harris et al. which teaches vancomycin in saline or 5% glucose with a pH of 4-7.5 for intravenous administration (column 6, lines 1-5). A pH of 4 reads upon claims 44 and 46. In claim 45 applicant

has claimed 4.5-6.9 which is encompassed by the range taught by Harris et al. however a pH close to 7 is considered ideal because it is neutral and therefore pHs close like 6.9 would have been obvious to one of ordinary skill in the art at the time of the invention. Neither Smith et al. nor Harris et al. describe the IV bag for intravenous administration, however those are known in the art, including those with the three distinct layers claimed by applicant. Mueller et al. teaches a multilayer film with an interior layer of ethylene/alpha-olefin copolymer, a middle (or first exterior) layer of high density polyethylene, and an exterior (or second exterior) layer of polyester (abstract). They further teach these films for use as IV bags (column 1, lines 1-20) and teach that their invention is better to withstand heat sterilization (column 1 line 60 to column 2 lines 67) and they further teach that their pouches have excellent optical properties (column 4 lines 27-35). They teach that ethylene/alpha-olefins layer contains polypropylene polymers and copolymers (column 7 lines 23-35) and thus their bags contain an inner layer that comprises propylene copolymer, a middle layer comprising polyethylene, and an outer layer comprising polyester. One of ordinary skill in the art would recognize that the bag of the instant claims is well within the teachings of Mueller et al. and it would have been obvious for one of ordinary skill in the art at the time of the invention to dissolve gancyclovir in a 5% glucose or saline solution and use a bag such as those taught by Mueller et al. for storage and administration. Thus claims 44-46 are unpatentable over Smith et al. in view of Harris et al. in further view of Mueller et al.

Conclusion

No claims are allowed.

Applicant's translation of the priority document necessitated the new rejections, because they are not based on amendments to the claims this action is non-final.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 7:30am-5pm Mon-Thu, 7:30am-4pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/580,651
Art Unit: 1614

Page 7

Meghan Finn

/James D Anderson/
Examiner, Art Unit 1614